Multiple behaviour change intervention for diarrhoea control in Lusaka, Zambia: a cluster randomised trial

Katie Greenland, Jenala Chipungu, Val Curtis, Wolf-Peter Schmidt, Zumbe Siwale, Mweetwa Mudenda, Joyce Chilekwa, James J Lewis, Roma Chilengi

Summary

Background Effective prevention and control of diarrhoea requires caregivers to comply with a suite of proven measures, including exclusive breastfeeding, handwashing with soap, correct use of oral rehydration salts, and zinc administration. We aimed to assess the effect of a novel behaviour change intervention using emotional drivers on caregiver practice of these behaviours.

Methods We did a cluster randomised controlled trial in Lusaka Province, Zambia. A random sample of 16 health centres (clusters) were selected from a sampling frame of 81 health centres in three of four districts in Lusaka Province using a computerised random number generator. Each cluster was randomly assigned 1:1 to either the intervention—clinic events, community events, and radio messaging—or to a standard care control arm, both for 6 months. Primary outcomes were exclusive breastfeeding (self-report), handwashing with soap (observation), oral rehydration salt solution preparation (demonstration), and zinc use in diarrhoea treatment (self-report). We measured outcome behaviours at baseline before start of intervention and 4–6 weeks post-intervention through repeat cross-sectional surveys with mothers of an infant younger than 6 months and primary caregivers of a child younger than 5 years with recent diarrhoea. We compared outcomes on an intention-to-treat population between intervention and control groups adjusted for baseline behaviour. The study was registered with ClinicalTrials.gov, number NCT02081521.

Findings Between Jan 20 and Feb 3, 2014, we recruited 306 mothers of an infant aged 0–5 months (156 intervention, 150 standard care) and 343 primary caregiver of a child aged 0–59 months with recent diarrhoea (176 intervention, 167 standard care) at baseline. Between Oct 20 to Nov 7, 2014, we recruited 401 mothers of an infant 0–5 months (234 intervention, 167 standard care) and 410 primary caregivers of a child 0–59 months with recent diarrhoea (257 intervention, 163 standard care) at endline. Intervention was associated with increased prevalence of self-reported exclusive breastfeeding of infants aged 0–5 months (adjusted difference 10·5%, 95% CI 0·9–19·9). Other primary outcomes were not affected by intervention. Cluster intervention exposure ranged from 11–81%, measured by participant self-report with verification questions. Comparison of control and intervention clusters with coverage greater than 35% provided strong evidence of an intervention effect on oral rehydration salt solution preparation and breastfeeding outcomes.

Interpretation The intervention may have improved exclusive breastfeeding (assessed by self-reporting), but intervention effects were diluted in clusters with low exposure. Complex caregiver practices can improve through interventions built around human motives, but these must be implemented more intensely.

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Department for Disease Control (K Greenland MSc, V Curtis PhD, W-P Schmidt MD), **Medical Research Council Tropical Epidemiology Group, Department for Infectious Disease Epidemiology** (J J Lewis PhD), **London School of Hygiene & Tropical Medicine, London, UK; and Centre for Infectious Disease Research in Zambia, Lusaka, Zambia** (J Chipungu BSc, Z Siwale BSc, M Mudenda MPh, J Chilekwa BSc, R Chilengi MD)

Correspondence to:
Katie Greenland, Department for Disease Control, London School of Hygiene & Tropical Medicine, London, UK
katie.greenland@lshtm.ac.uk

Introduction

Seemingly simple, inexpensive interventions that can prevent most diarrhoea morbidity and mortality have been available for many years, yet diarrhoea remains one of the biggest killers of children worldwide.[1]

In 2009, WHO and the United Nations Children's Fund (UNICEF) called for implementation of the 7-point plan, a comprehensive strategy for diarrhoea control based on seven curative and preventive interventions: fluid replacement to prevent diarrhoea, typically through use of low-osmolarity oral rehydration salts (ORS); treatment with zinc; water, sanitation, and hand hygiene interventions; rotavirus and measles vaccination; exclusive breastfeeding; and vitamin A supplementation.[2] The widespread adoption of diarrhoea control measures could prevent 95% of child mortality from diarrhoea by 2025.[3] These control measures could subsequently reduce susceptibility to pneumonia [4] and undernutrition,[5] and improve cognitive development.[6] In reality, these benefits are limited because of low coverage and uptake of these interventions, particularly in those most at risk.[3]

Exclusive breastfeeding is associated with reduced childhood diarrhoea mortality and morbidity,[7] and quicker recovery during illness,[8] particularly when infants are exclusively breastfeed for the first 6 months of life,[9] yet fewer than 40% of infants aged 0–5 months are breastfeed exclusively.[10] Handwashing with soap can prevent up to 40% of diarrhoeal episodes, yet only about

Research in context

Evidence before this study

Existing knowledge on drivers of each behaviour and the effectiveness of community-based intervention strategies to influence them was considered through literature search, review of previous work in Zambia, and a framing workshop held in December, 2012, which brought together all sources of information to map what was known and not known about the target behaviours ahead of formative research conducted before intervention development. This process followed the Behaviour Centred Design Approach. Emotional drivers have been previously used in public health interventions, but to our knowledge affiliation and disgust motives have not been used to instigate change in the other targeted behaviours.

Added value of this study

This theory-based, multi-faceted intervention brought a fresh approach to the ongoing challenge of behaviour change that continues to impede diarrhoeal disease control programmes in Africa and elsewhere. The intervention tested here succeeded in improving self-reported rates of exclusive breastfeeding of infants aged 0–5 months, despite low intervention exposure. In areas where exposure was higher the intervention appeared to be more effective across other behaviours. Collectively, this suggests that the intervention might have succeeded in attaching a new motivation to breastfeeding behaviour and, if adapted and delivered in a way that achieves greater reach in a community, this approach could be used to improve other behaviours too.

Implications of all the available evidence

Clinic interventions on breastfeeding should be complemented by community-based strategies, usually involving peer-to-peer individual or group counselling sessions. This trial suggests that a package that also includes elements of the Komboni Housewives intervention could potentially be more effective. The trial also provides support for increased investment in the development of approaches based on emotional drivers of behaviour.

19% of people worldwide wash their hands with soap after using the toilet.[11] ORS prevents and reverses dehydration caused by diarrhoea,[10] but only a third of diarrhoeal episodes are treated with ORS,[10] and administered ORS might be prepared incorrectly.[12] Zinc is also an effective therapy,[13] but its use is uncommon.[10]

In Zambia, diarrhoea is a major cause of child mortality.[14] 73% of mothers report that they exclusively breastfeed their infants aged 0–5 months, but 39% of infants aged 4–5 months are given complementary foods,[14] a decision that is often influenced by the social environment.[15] Only 13% of homes have both a specific place for handwashing and soap and water available at this location,[14] which suggests suboptimal handwashing practice.[16] The population is familiar with ORS and it is reportedly used to treat 64% of diarrhoeal episodes,[14] but fewer than 30% of ORS solutions are prepared correctly, inhibited by aspects of the physical environment such as difficulty measuring 1 L of water accurately and reluctance to use a whole sachet of salts to make up ORS solution.[17] Zinc is largely unknown by caregivers as a diarrhoea treatment.[17]

The gap between best practice and reality represents a major behaviour change challenge for the public health community. Behaviour is influenced by the physical, social, and biological environment and our conscious and unconscious responses to it through a complex array of interacting and often interdependent factors.[18] Interventions that seek to improve behaviour by manipulating one or more of these factors can be more effective than standard health education.[11,19] To improve intervention science and thereby the effectiveness of behaviour change interventions, innovative, theory-based campaigns need to be developed and rigorously assessed.[20] This is particularly important when interventions are complex and target multiple behaviours for change simultaneously.[21]

We test the hypothesis that an innovative behaviour change campaign targeted at caregivers of children younger than 5 years can improve multiple caregiver behaviours concerning diarrhoea prevention and treatment. We designed a novel intervention to improve multiple behaviours related to diarrhoea prevention and management in Zambia by associating their practice with new motivations elicited through emotional demonstrations and a unifying campaign theme. In this Article, we report the effect of this unconventional campaign on caregiver practice of exclusive breastfeeding, handwashing with soap, and use of correctly prepared ORS and zinc to treat childhood diarrhoea.

Methods

Study design and participants

We did a cluster randomised trial in Lusaka Province, Zambia, between Jan 20 and Nov 7, 2014. Clusters were defined as clinic catchment areas, as the intervention was predominantly delivered at clinics and via community events. 16 clinics were randomly selected from a list of 81 government clinics in three of the four districts of the province. One district was excluded for pragmatic reasons as it is sparsely populated.

The intervention targeted primary caregivers of children younger than 5 years, but the assessment was restricted to two specific populations: mothers of an infant younger than 6 months and primary caregivers of a child younger than 5 years with recent diarrhoea. Diarrhoea was defined by the WHO definition as three or more loose stools within 24 h, or more frequent motions than usual for the

individual.[22] Recent was defined as the last 7 days to reduce recall bias.[23] Baseline and follow-up surveys were independent random samples, as caregivers of children eligible at baseline would not have all been eligible at follow-up. The follow-up sample excluded individuals who had moved into the area since baseline.

Randomisation and masking

Clusters were randomly selected within three strata based on district in a 2:1:1 ratio, resulting in a sample that was half peri-urban (Lusaka district) and half rural (Chongwe and Kafue districts). A statistician unrelated to the study allocated half of the clusters in each district to intervention or control (no intervention, standard care at clinics) using a random number table. Randomisation was done before baseline data collection took place, but cluster allocation was concealed from the study team until after baseline data had been collected.

Participants could not be masked to the intervention. Outcome assessors were not involved in delivering the intervention and were not informed where the intervention had taken place.

Komboni Housewives intervention

Campaign development followed the Behaviour Centred Design approach, a 5-step process for the design and testing of behaviour change interventions: assess what is known and what is not known about the behavioural problem; build on this work by doing formative research on the factors inhibiting and facilitating practice of the target behaviour(s); and create, deliver, and evaluate a theory-based intervention.[24] These steps in themselves are not novel, but the process is a helpful way of ensuring the tested intervention is grounded in theory about the determinants of behaviour.

The formative research was guided by the Evo–Eco theory of behavioural determinants [18] that gives equal weight to understanding how psychological (automated or habitual, motivated, and rationalised) factors and environmental (physical, social, and biological) factors influence behaviour with a view to identifying possible solutions to behavioural problems. This theory was previously used to inform the design of interventions in other settings.[25,26] Formative research revealed that knowledge about good childcare practices was widespread, but handwashing and feeding behaviour were suboptimal, ORS was incorrectly prepared, and awareness of zinc as a treatment was low. Results of the formative research also showed that women seek to avoid being a source of gossip in their community.[15,17] Associating practice of a given behaviour with a new motivation might facilitate behaviour change in an enabling environment and the decision was made to build the campaign around the motive of affiliation, the drive to become an accepted member of a given social group.[27] The aim was to associate practice of the target behaviours with achievement of social approval and imply that the target behaviours were substantively normative.

The campaign, developed with creative agency DDB Iris, centred on a group of women known as Adzimayi Bamu Komboni, meaning housewives of the slum community. This group gossiped about women whose behaviour was believed to deviate from the target behaviours, but they ultimately admitted women into

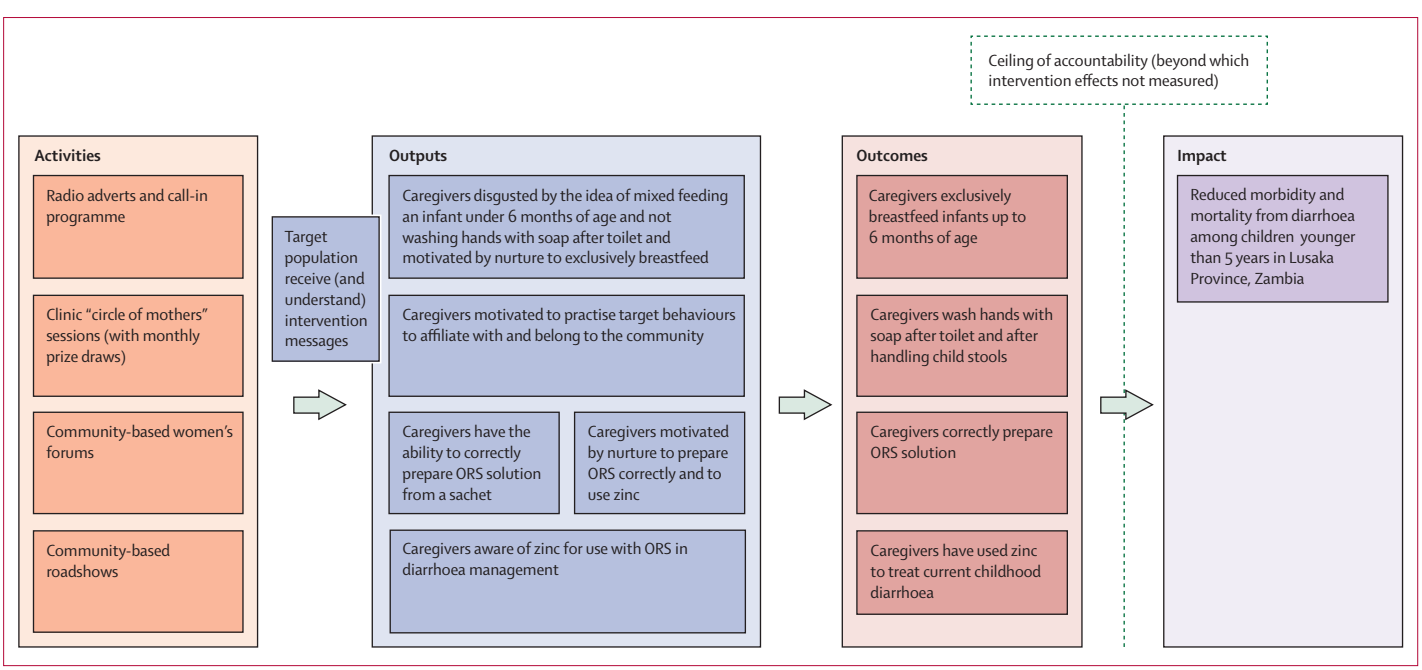

Figure 1: **Simplified Theory-of-Change Model of the Komboni Housewives Intervention**
ORS=oral rehydration salts.

	Target audience	Setting	Implementers	Content	Delivery
Radio adverts and call-in show	Population in target areas, particularly caregivers of children younger than 5 years	Broadcast on three radio stations: Komboni Radio, Radio 1, and Radio 4	Komboni Housewives and radio MCs	Airing of three different spot adverts (EBF, HWWS, ORS+Zinc); similar content to that described in the forum and roadshows skits; call-in shows used as a discussion forum and to amplify the activities of the women's forums (the timing of the shows coincided with the women's forums); discussions scripted around the target behaviours to test the callers' understanding of the intervention messages; jingle about the target behaviours also played	Three times a week for 6 months, with penetration in both intervention and control areas
Komboni Housewives women's forums	About 20 caregivers of children younger than 5 years	Forums held in the community at the home of a host (an intervention recipient)	Komboni Housewives	All four behaviours targeted using skits (featuring the Komboni Housewives gossiping about mothers they believe are not practising the correct behaviours, being proven wrong and welcoming the mother into their group); discussion with question and answer sessions; emotionally engaging demonstrations (designed to evoke feelings of disgust at mixed feeding a baby younger than 6 months and not handwashing with soap, and nurture in relation to incorrect preparation of ORS); and short films featuring the Komboni Housewives (introduced partway through the intervention period); activities were supported by banners, certificates, stickers, a branded bus, and prizes (hats and T-shirts)	One or two forums per day throughout intervention period; rotating between the eight intervention areas
Circle of mothers initiative (with monthly prize draw)	Caregivers of children younger than 5 years (preferentially those with a child presenting with diarrhoea)	At the ORT corner (where ORS solution is traditionally available) or another designated area in the government clinic in each intervention area	Two Neighbourhood Health Committees linked to the clinic in each site	Circle of mothers: content similar to forums designed to be shorter and focused on exclusive breastfeeding and ORS and zinc Prize draws: winner of a hamper selected from all caregivers who attended the clinic session in the previous month; the Komboni Housewives did a mini forum at select prize draws	Every Monday–Friday at clinics in all eight sites Monthly in each site; attended by Komboni Housewives once per site
Roadshows	All community members	Large public space in each site	MCs and Komboni Housewives (featuring a well-known local musician, Afunika)	Large roadshows, one in each intervention area. Similar content to the forums but energised by the presence of the MCs and the presence of Afunika who sang the campaign song, engaged the audience in discussion about the target behaviours; discs featuring the campaign song, hats, and T-shirts were given to those giving correct answers in a quiz	One roadshow in each site

MC=master of ceremonies. EBF=exclusive breastfeeding. HWWS=handwashing with soap. ORS=oral rehydration salts. ORT=oral rehydration therapy.

***Table 1*: Overview of intervention content and delivery schedule**

their social circle (a reward) when it was proven that they were practising the correct behaviours. The motives of disgust (an adaptive mechanism that helps us to avoid disease) and nurture (a natural instinct to protect and care for one's offspring)[27] were also used to drive behaviour change through elicitation of strong emotional responses in connection with the targeted behaviours. All elements were piloted to assess acceptability and comprehension.

The campaign had four components: women's forums delivered in neighbourhoods; roadshows delivered in public gathering spaces; clinic-based circle of mothers sessions with monthly prize draws; and call-in programmes on local radio linked to the forums. Women's forums were small group events in people's homes involving mothers of children younger than 5 years. Roadshows were large gatherings designed to draw the whole community and raise awareness of the campaign. Clinic sessions were small-scale versions of the forums with a focus on ORS and zinc. The radio programmes discussed myths and challenges around the target behaviours and were broadcast in intervention and control areas. The community activities (forums and roadshows) were delivered by a troupe of actors, and pairs of Neighbourhood Health Committee volunteers affiliated with the clinics and already known in the communities delivered the clinic sessions at each clinic. Eligible individuals had the opportunity to attend each event, ranging in duration from 45 min (clinic sessions) to several hours (roadshows). Figure 1 shows a simplified theory of change for the intervention.

For more on the **Komboni Housewives intervention** see http://kombonihousewives.lshtm.ac.uk

The target behaviours were addressed through a combination of role play, skills demonstrations (eg, the correct preparation of ORS), visual, interactive demonstrations designed to evoke strong emotional responses, question and answer sessions, quizzes, video adverts shown on screens, dance, and prize giving. Table 1 provides an overview of intervention content and delivery during the 6-month implementation period. The Komboni Housewives intervention ran from mid-March to mid-September, 2014.

Outcomes

This is an assessment of a complex intervention with analyses of endpoints measuring multiple behaviours. As such, we designated one endpoint as primary for each of these behaviours (and others as secondary). We defined four primary outcomes: exclusive breastfeeding of infants aged 0–5 months (by self-report); handwashing

after risk of contact with faeces (by structured observation); the correct preparation of oral rehydration solution (by demonstration); and the use of zinc to treat childhood diarrhoea (by self-report). No health outcomes were measured.

In accordance with WHO definitions, exclusive breastfeeding was defined as a child having received no food or drink besides breastmilk, vitamins, or medicines in the preceding 24 h.[28] The number of faeces-related events associated with handwashing with soap was measured by direct observation.[29] ORS preparation was observed using a structured checklist, with correctly-mixed solution defined as the combination of a whole sachet of ORS with 1 L of clean (boiled or chlorinated) water. Zinc use referred to reported treatment of current childhood diarrhoea with zinc.

Secondary outcomes were exclusive breastfeeding of infants 0–2 months; predominant breastfeeding of infants aged 0–5 months (consumption of water and water-based drinks or fruit juice alongside breastmilk, vitamins, and medicines);[28] handwashing with soap at key times (associated with food handling and risk of contamination with faeces); use of soap on the occasions hands are washed; presence of ORS sachets within the home; treatment of the current episode of diarrhoea with ORS; previous use of zinc; and awareness of zinc as a diarrhoeal treatment.

Sample size

The required sample size was calculated for each of the primary outcomes and the largest sample size needed to detect a 20% absolute increase in the prevalence of correct preparation of ORS (from 30% to 50%) with 80% power, a two-sided alpha of 0·05 and an intraclass correlation coefficient (ICC) of 0·01 [25] was adopted. Assuming a cluster size of 20 individuals resulted in a design effect of 1·19 and 120 individuals, in six clusters per group. To allow for the uncertainty in the ICC and possibly lower effect sizes, we increased the sample size by two clusters per arm, resulting in eight clusters per arm with 160 individuals per group. To improve the scope for process documentation and secondary analyses an additional ten eligible individuals were recruited in each intervention cluster at follow-up.

Procedures

Breastfeeding and handwashing outcomes were assessed in mothers of infants younger than 6 months and ORS and zinc outcomes were measured in primary caregivers of a child younger than 5 years with recent diarrhoea. Outcomes were measured through cross-sectional surveys done at baseline and at follow-up, 4–6 weeks after the end of the intervention. Handwashing outcomes were measured through a 3 h period of structured observation (from 0600 h to 0900 h, or 1100 h to 1400 h) done before survey administration. Data were also collected on sociodemographic variables and water and sanitation facilities. Exposure to any components of the Komboni Housewives was also captured at follow-up. Surveys were piloted and administered in the preferred language of the participant (usually Nyanja or English).

We based sampling in each peri-urban cluster on the so-called fried egg design,[30] whereby sampling was restricted to a defined sampling area around each clinic (the egg yolk) and not the full catchment area. We mapped and divided the area into four segments, with recruitment within each segment beginning at a randomly selected starting point and thereafter following a random walk according to a protocol to guide the direction of this walk. We left a gap of three households (one in rural areas) each time an eligible individual was identified. We sought basic demographic information from eligible non-participants, and we revisited eligible houses if the caregiver was absent or busy.

Enumerators were all female, educated beyond high school, and familiar with doing research studies. They underwent a week of training including classroom and practical sessions.

Ethics and consent

We obtained written informed consent or a witnessed thumbprint from all participants and eligible non-participants who volunteered demographic data in the baseline or endline surveys. The study protocol was approved by the ethics board at the London School of Hygiene & Tropical Medicine (approval number 6493) and by the University of Zambia Biomedical Research Ethics Committee (ref 001-09-13). The Ministry of Health also gave permission for the study.

Statistical analysis

Data were double entered into Epi Data 3.1 and cleaned using Stata 14 (StataCorp 2015, College Station, TX, USA). We checked discrepant entries against original paper surveys and did consistency checks. We recoded variables and did principal component analysis to compute wealth quintiles.[31]

We did the primary analysis on an intention-to-treat basis. We computed cluster summaries for each behavioural outcome as the means of cluster means.[30] We used an unpaired *t* test to compare crude proportions between study groups and compute confidence intervals. We calculated the ICC for each behavioural outcome. The analysis plan prespecified that analyses were adjusted for baseline measures of each respective outcome. We did not adjust for multiple testing, as any change in a target behaviour was assessed separately.[32]

We used standard methods for trials with few clusters to analyse all endpoints,[30] giving each cluster equal weight, and followed the two-step approach recommended by Hayes & Moulton to adjust for cluster baseline values of each outcome measure.[30] This approach involved logistic regression of binary behavioural outcomes and baseline levels of behaviour

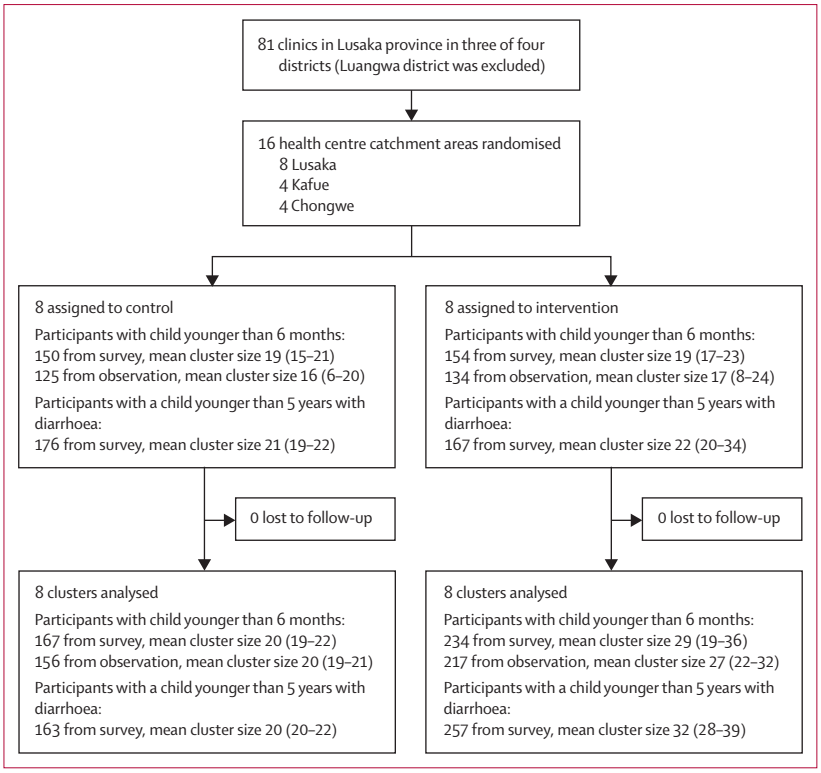

***Figure 2*: Trial profile**

using individual household data, ignoring clustering and treatment arm allocation, and subsequently comparing cluster residuals. We adjusted breastfeeding rates for infant age (prespecified primary analysis). We estimated adjusted effect measures and 95% CIs following the approach recommended by Hayes and Moulton, as described previously, replacing cluster proportions with the baseline adjusted residuals and adjusting the p value and 95% CIs by reducing the degrees of freedom by 1. We assessed intervention exposure in all surveyed households in intervention and control clusters at the close of each survey. We defined intervention exposure as self-reported attendance at one or more of the following intervention components: women's forum; clinic circle of mothers session or prize draw; or roadshow. We asked verification questions requiring the participant to provide more detail about the event attended. As variability in exposure to the intervention was anticipated, we planned subgroup analysis based on exposure. Intervention clusters were grouped into high exposure (more than 30% of a cluster) and low exposure (less than 30% of a cluster) post hoc. We designed the clinic sessions to be shorter to avoid burdening caregivers with an ill child, so these sessions did not contain handwashing messages; the exposure variable for handwashing outcomes was modified accordingly. We measured exposure to the radio show, but did not adjust for this. The study was registered with ClinicalTrials.gov, number NCT02081521.

See Online for appendix

Role of the funding source

The funders of the study reviewed the study protocol but had no role in the choice of study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Baseline data were collected in January–February, 2014, and endline data were collected in October–November, 2014 (figure 2). Baseline profiles of participants were similar for most sociodemographic characteristics and prevalence of behaviours, though there were differences between the study groups in both survey profiles with respect to educational level, employment status, prevalence of shared sanitation, awareness of zinc, and use of ORS and zinc (table 2). Only 13 eligible individuals declined to participate in the study at either baseline or endline.

The mean age of infants included in the survey of infants younger than 6 months at follow-up was similiar between study arms (control 3·0 months; intervention 2·9 months). 92% of birth dates in each arm were verified using the health card for children younger than 5 years. Breastfeeding was initiated after birth by almost all mothers (98% control *vs* 99% intervention). There was good evidence that the proportion of mothers practising exclusive breastfeeding of infants aged 0–5 months at follow-up was 11% higher in the intervention arm than in the control arm (95% CI 0·9–19·9, table 3).

Figure 3 presents age-specific prevalence of exclusive breastfeeding at follow-up; exclusive breastfeeding was more common in the intervention arm than in the control arm in all but one age group.

Despite differences in baseline levels of behaviour, the measured change in exclusive breastfeeding rates was seen in both rural and urban areas (appendix).

49 (12%) of 394 households did not have any soap in the home for handwashing. 1255 events involving risk of contact with faeces (after toilet, or after cleaning up or disposing of a child's stool, n=268) or food handling (preparation, eating or feeding a child, n=987) were recorded in 373 households during observation of female caregivers at follow-up. Handwashing with soap was observed on 32% of faeces-related events (primary outcome) in the intervention group and 28% of events in the control group, no different from baseline (adjusted difference 4%, 95% CI –19·3 to 27·8). No difference was reported in rates of handwashing in relation to food handling (5·6% intervention *vs* 6·8% control, adjusted difference –1·3%; –5·7 to 3·2), or at any key time for handwashing (table 3). Use of soap or soapy water on occasions when hands were washed was also unchanged. Handwashing rates between the two groups did not differ by educational level or wealth quintile (data not shown).

Only four participants at follow-up declined to prepare ORS. There was weak evidence that ORS was correctly

	Caregiver of child younger than 6 months (N=306)				Caregiver of child younger than 5 years with diarrhoea (N=343)			
	N	Control (n=150)	N	Intervention (n=156)	N	Control (n=167)	N	Intervention (n=176)
Household size, median (IQR)	146	5 (4–7)	153	5 (4-7)	167	6 (4–7)	176	5 (4–7)
Age of caregiver in years, median (IQR)	141	27 (23–33)	149	26 (21–31)	159	28 (24–34)	169	26 (22–32)
Age of eligible child in months, median (IQR)	150	3 (3–4)	154	4 (3-5)	160	27 (16–40)	163	21 (15–32)
Resident at address for 3 months or less	150	13 (8%)	154	20 (13%)	167	16 (10%)	176	24 (14%)
Married or living with partner	149	117 (79%)	152	126 (83%)	165	130 (79%)	171	124 (73%)
Highest education level of caregiver								
None	148	9 (6%)	151	5 (3%)	164	5 (3%)	176	12 (7%)
(Some) primary	148	59 (40%)	151	51 (34%)	164	77 (47%)	176	75 (43%)
(Some) secondary	148	59 (40%)	151	85 (56%)	164	67 (41%)	176	80 (46%)
Higher education	148	21 (14%)	151	10 (7%)	164	15 (9%)	176	9 (5%)
Employment status of caregiver								
None	149	100 (67%)	154	122 (79%)	165	113 (69%)	176	143 (81%)
Part-time	149	32 (22%)	154	25 (16%)	165	44 (27%)	176	25 (14%)
Full-time	149	17 (11%)	154	7 (5%)	165	8 (5%)	176	8 (5%)
Asset-derived wealth quintile*								
Poorest	146	46 (35%)	144	41 (32%)	137	46 (34%)	135	46 (34%)
Middle	146	42 (32%)	144	45 (35%)	137	46 (34%)	135	48 (36%)
Least Poor	146	44 (33%)	144	42 (33%)	137	45 (33%)	135	41 (30%)
Household shares sanitation facility	141	70 (49%)	146	105 (72%)	147	90 (61%)	164	109 (67%)
Number of clusters	..	8	..	8	..	8	..	8
Number of individuals per cluster, mean (SD)	..	19 (2·2)	..	19 (2·0)	..	21 (1·0)	...	22 (4·9)
Ratio of urban to rural clusters	..	1:1	..	1:1	..	1:1	..	1:1
Behaviours								
Infants 0–5 months exclusively breastfed	150	45% (20.7)	156	39% (10.1)	..	..	..	..
Hands washed with soap†	189	22% (14·7)	224	25% (15·8)	..	..	..	..
Caregivers preparing ORS correctly	..	..	..	..	146	34% (15·8)	151	33% (13·5)
Diarrhoeal episodes in children younger than 5 years given ORS	..	..	..	..	151	58% (19·2)	158	69% (16·1)
Diarrhoeal episodes in children younger than 5 years given zinc	..	..	..	..	164	5% (6·4)	168	9% (10·7)
Caregivers who have heard of zinc	..	..	..	..	166	16% (9·4)	170	25% (18·4)
Caregivers who have ever used zinc	..	..	..	..	164	8% (11·0)	168	12% (11·6)

Values for individual variables are numbers (%) or median (IQR), and values for cluster variables are mean proportions (SD). ORS=oral rehydration salt solution. *Derived from principal component analysis of 13 household assets (ownership of home, television, mobile telephone, land for farming, non-domestic animals, car, fridge, freezer, bicycle, radio, water tap inside the home, electricity, flush latrine) and material of structure (cement *vs* mud floor, cement or brick *vs* mud wall). †Hands washed with soap or soapy water after toilet, or after cleaning up or disposing of a child's stool, as mean % of all toilet and child defecation events. Handwashing outcomes measured by observation of 681 events in 125 households in the control group and 913 events in 134 households in the intervention group. All behaviours measured as described in the text.

***Table 2*: Baseline characteristics of participants in the two study populations by intervention allocation**

prepared more frequently in the intervention group than the control group (49% *vs* 38%, adjusted difference 13%; –0·5 to 25·7, table 3). Observation of ORS preparation revealed errors mostly concerning the measurement of 1 L of water, with only 139 of 247 participants in the intervention group and 70 of 163 participants in the control group doing this correctly at follow-up (adjusted difference 14%, –1·9 to 29·0, p=0·08; data not shown). The intervention had no effect on reported use of ORS to treat diarrhoea or prevalence of storage of ORS at home (table 3).

Participants in the intervention groups were no more likely to have used zinc to treat current diarrhoea than were those in the control group (adjusted difference 3%, –6·6 to 12·9; p=0·50). The proportion of participants who had ever used zinc increased by 9%, but confidence intervals were wide (95% CI –3·1 to 20·7).

Awareness of zinc as a diarrhoea treatment was substantially higher in the intervention group (25% higher, 11·0–39·1; table 3), an indication that individuals exposed to the intervention had retained this message.

	Control N, % (SD)	Intervention N, % (SD)	Unadjusted effect size (95%CI)	Unadjusted effect p value	Adjusted effect size (95%CI)	Adjusted effect p value
Exclusive breastfeeding						
Exclusive breastfeeding of infants aged 0–5 months	161, 50·5% (12·7)	234, 60·9% (10·7)	10·4% (–2·2 to 23·0)	0·10	10·5% (0·9 to 19·9)	0·03
Handwashing with soap						
Handwashing with soap after risk of contact with faeces*	128, 28·4% (17·7)	130, 32·2% (25·8)	3·8% (–20·0 to 28·5)	0·74	4·2% (–19·3 to 27·8)	0·71
Oral Rehydration Salts						
Caregivers able to correctly prepare ORS	163, 37·6% (12·1)	247, 49·0% (4·9)	11·5% (–2·6 to 25·4)	0·10	12·6% (–0·5 to 25·7)	0·06
Zinc						
Current diarrhoeal episodes in children younger than 5 years treated with zinc	165, 16·3% (9·9)	248, 19·4% (8·2)	3·1% (–6·6 to 12·8)	0·49	3·2% (–6·6 to 12·9)	0·50
Exclusive breastfeeding						
Exclusive breastfeeding of infants aged 0–2 months	75, 67·0% (27·8)	119, 79·3% (17·6)	12·2% (–12·7 to 37·1)	0·31	13·6% (–8·6 to 35·8)	0·21
Predominant breastfeeding of infants aged 0–5 months	161, 61·8% (16·2)	234, 73·9% (10·2)	12·1% (–2·4 to 26·7)	0·09	11·7% (1·2 to 22·2)	0·03
Handwashing with soap						
Handwashing with soap at key times†	498, 12·8% (7·4)	694, 11·0% (5·9)	–1·8% (–8·9 to 5·3)	0·60	–1·7% (–8·8 to 5·4)	0·62
Soap use on occasions when hands are washed‡	399, 29·4% (10·7)	543, 30·0% (9·8)	0·5% (–10·4 to 11·5)	0·92	0·5% (–11·4 to 10·5)	0·93
Oral rehydration salts						
ORS sachet(s) present within the home	101, 33·7% (16·8)	145, 39·8% (12·9)	6·1% (–9·9 to 22·1)	0·43	6·4% (–7·7 to 20·4)	0·35
Current diarrhoeal episodes in children younger than 5 years treated with ORS	169, 57·8% (13·3)	259, 54·7% (6·6)	–3·1% (–14·4 to 8·2)	0·56	–3·2% (–14·5 to –8·0)	0·55
Zinc						
Caregivers have heard of zinc	169, 32·5% (11·9)	259, 61·2% (14·3)	28·6% (14·5 to 42·8)	<0·001	25·1% (11·0 to 39·1)	0·002
Caregivers have ever used zinc to treat diarrhoea in children younger than 5 years	165, 19·4% (13·4)	248, 30·5% (11·9)	11·1% (–2·5 to 24·7)	0·10	8·8% (–3·1 to 20·7)	0·13

ORS=oral rehydration salt solution. *After toilet, or after cleaning up or disposing of a child's stool. †Before handling food (before preparing or eating a meal, or before feeding a child), or after risk of contact with faeces (after toilet or after cleaning up or disposing of a child's stool. ‡Proportion of occassions (key times or other time) when hands were observed to be washed that were accompanied by soap use.

***Table 3*: Effect of the intervention on behavioural outcomes**

In total, 99 (38%) of 259 caregivers of children younger than 5 years with diarrhoea and 95 (41%) of 234 mothers of children younger than 6 months in the intervention group were exposed to at least one face-to-face intervention component. A third of these individuals in each survey attended more than one component. Four control group survey participants reported having attended an intervention event. Self-reported intervention exposure varied considerably between intervention clusters, ranging from 11–81%. Adjusted prevalence differences of the primary outcomes for all four behaviours were 8–16% higher when high exposure intervention clusters were directly compared with control clusters, (table 4, figure 4). Previous use of zinc in high exposure clusters was also higher than in control clusters (adjusted difference 17%, 95% CI 13·2–31·3, p=0·02).

Reported exposure to the Komboni Housewives radio show was higher in the intervention group than in the control group (30% *vs* 16% in children younger than 5 years, 38% *vs* 24% in children younger than 6 months). Excluding control group individuals who had heard the

radio show did not greatly alter cluster prevalence of the target behaviours in the control group.

Discussion

The effect assessment of the innovative Komboni Housewives multiple behaviour change campaign in Lusaka Province, Zambia revealed that the intervention had a positive effect on exclusive breastfeeding of infants aged 0–5 months. The intervention also succeeded in raising awareness of zinc as a diarrhoea treatment, a prerequisite for use. There was weak evidence in support of an improvement in caregiver ability to prepare ORS solution. The intervention did not increase the use of ORS and zinc to treat diarrhoea or handwashing with soap. The trial further highlights some of the challenges associated with assessing complex behaviour change interventions, such as effect dilution due to limited intervention coverage and the potential of bias due to the use of self-reported outcomes and reactivity under direct observation of participants.

The extent to which we interpret the trial findings as evidencing intervention success depends on the amount of change we consider sufficient to conclude that an intervention has worked. As the relationships between practice of each of the target behaviours and diarrhoea morbidity and mortality are well established, an intervention that improves any of these risky practices could have potentially important implications. The intervention was associated with important changes in the primary outcomes for two of the four behaviours when analysis was restricted to clusters where intervention exposure was higher, suggesting that this approach deserves further development.

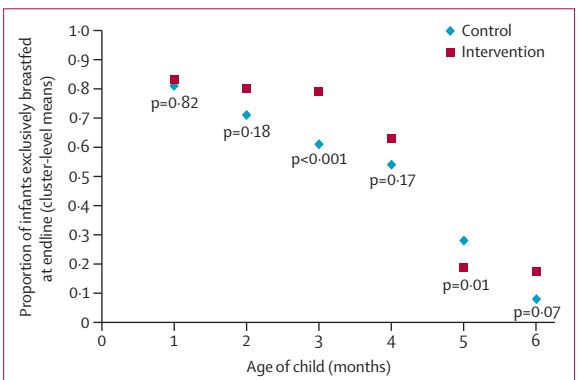

Figure 3: **Proportion of infants exclusively breastfed at follow-up, by age and trial group**

Peer individual and group counselling interventions have successfully improved breastfeeding exclusivity in a range of low-income settings.[33] These interventions are often implemented by community health workers via the clinic, and few trials have assessed community initiatives.[34] This trial adds to this body of evidence and suggests that this approach potentially offers a sustainable community-based intervention that could complement peer support and counselling.

Use of ORS did not increase as a result of the intervention, but there was weak evidence that skill in making it correctly did increase. Few high-quality studies exist on the effectiveness of ORS promotion strategies so it is difficult to position these findings within the wider literature;[35] nonetheless, co-promotion of ORS and zinc can enhance ORS uptake [36] and this did not take place in our study. It is possible that the levers for change for correct ORS preparation were stronger than those used to promote its use. Diarrhoea severity and access to manufactured ORS and zinc might have also influenced caregiver actions.

The intervention succeeded in raising awareness of zinc. Use of zinc to treat current diarrhoea did not increase in areas where the intervention was more intensively delivered, but the prevalence of ever having used zinc to treat childhood diarrhoea did improve. Awareness of zinc as a treatment for diarrhoea is an important first step, because caregivers often prefer to use medicines they know and trust.[17] Low quality data on zinc supply prohibit

	Control clusters (N=8) %, (SD)	Low exposure clusters (N=4) %, (SD)	Low exposure unadjusted effect size (95% CI)	Low exposure adjusted effect size (95% CI)	High exposure clusters (N=4) %, (SD)	High exposure unadjusted effect size (95% CI)	High exposure adjusted effect size (95% CI)
Exclusive breastfeeding 0–5 months	50·5% (12·7)	57·8% (12·7)	7·3% (–10·0 to 24·6)	12·8% (0·8 to 26·5)	64·0% (8·9)	13·5% (–2·5 to 29·4)	13·8% (2·7 to 24·9)†
Handwashing with soap after risk of contact with faeces*	28·4% (17·7)	17·3% (11·1)	–11·1% (–33·0 to 10·7)	–10·3% (–31·6 to 11·1)	47·1% (29·0)	18·7% (–10·9 to 48·3)	12·4% (–15·6 to 40·5)
Caregivers able to correctly prepare ORS	38·0% (12·4)	44·4% (18·9)	6·4% (13·6 to 26·4)	8·3% (–9·6 to 26·2)	53·7% (6·2)	15·7% (0·8 to 30·6)†	16·1% (2·4 to 26·7)†
Current diarrhoeal episode in children younger than 5 years treated with zinc	15·6% (9·3)	15·3% (4·2)	0·4% (–11·4 to 10·7)	0·2% (–11·4 to 11·0)	23·5% (9·7)	7·8% (–5·0 to 20·7)	7·8% (–5·1 to 50·7)

Low exposure clusters=15–28% exposure to at least one face-to-face intervention component. High exposure clusters=35–66% exposure. Adjusted for cluster baseline levels of behaviour and, for exclusive breastfeeding only, age of the infant. ORS=oral rehydration salt solution. *After use of toilet, after cleaning up a child's stools. †p<0·05.

Table 4: **Effects of intervention exposure on key behavioural outcomes**

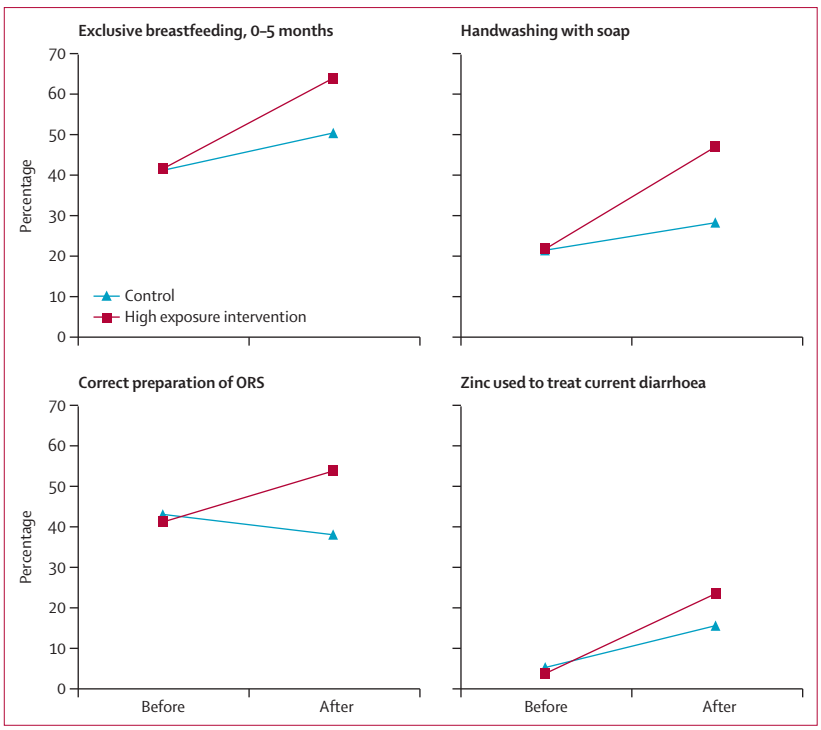

Figure 4: **Comparison of trends in primary outcomes before and after the intervention in control clusters (n=8) and high exposure intervention clusters (n=4)**

assessment of the extent to which availability is likely to have limited uptake, but as zinc availability at clinics and local pharmacies was ensured during the trial but not thereafter this could explain why the number of caregivers who had previously used zinc increased, but zinc use for current episodes did not change. Zinc use in the control group increased from baseline to follow-up. This could be due to exposure to radio messaging (reported by almost one in five5 control group participants), but might also be due to external influence, such as ongoing training of health workers on diarrhoea management and action to improve supply chain.

We did not find an improvement in handwashing behaviour. One key difference between this trial and a previous trial by our group that improved handwashing behaviour in rural India [25] is that the Indian intervention only targeted handwashing practices. Proponents of single behaviour change interventions stress the importance of minimising the number of messages and behaviours to avoid message dilution and overloading of the target population.[37] Those advocating for multiple behaviour change argue that interventions tackling multiple risk factors or disease transmission routes might produce the greatest eventual effect on health in the least resource-intensive manner.[38] Although the Komboni Housewives intervention was only 6 months long and did not explicitly compare delivery of single and multiple interventions, the heterogeneity of intervention effect suggests that some intervention messages might have overshadowed others. It is possible that handwashing messages were less stimulating and novel than the other activities. The results suggest that it might be harder to achieve substantial changes in behaviour when the requisite infrastructure or supplies are absent from households or are kept in an inconvenient place: although 88% of households had soap available for handwashing, 75% of these households kept the soap inside even though hands were washed outside; only 25 of 395 households used a handwashing station when asked to demonstrate how they usually wash hands. Caregivers might need further support through sustained intervention to help them create an enabling physical environment to support handwashing behaviour, [39] but focusing on infrastructure should not preclude efforts to improve important public health behaviours.

The intervention was most successful in clusters where exposure was greatest, which were either rural sites or lower socioeconomic status slum areas. Further exploration of the factors affecting intervention exposure is warranted. It is plausible that the intervention was more successful at changing norms and creating the impression that everybody practises the target behaviours in clusters with higher exposure because messages diffused better through the community. Intervention effects might have been greater if the intervention had continued for longer, allowing time for messages to infiltrate the community.

This study was not powered to analyse effect by component, but exploratory analysis suggests that the high interpersonal contact in the forums was more influential than activities such as the roadshows. If roadshows did not directly influence behavioural outcomes, categorisation of roadshow attendees as exposed might have biased effect estimates towards the null. Furthermore, as individuals could have been exposed to the intervention at any point during the 6-month implementation period, the time between exposure and outcome measurement might have influenced measured effect sizes, particularly for breastfeeding outcomes, where an individual might have been exposed after they had initiated mix-feeding. A cohort design might be preferable in a future study of a similar programme.

The radio element of the Komboni Housewives campaign was included to raise awareness of the intervention target behaviours and to help legitimise community activities. The downside of this is that individuals in the control group were also exposed. A greater proportion of intervention group participants reported exposure to the radio messages, suggesting differential recall bias between study groups. The messages are likely to have been stronger in the intervention areas as the radio show was linked to some of the forums and participants answered questions live on air.

Measurement of behaviour can be prone to social desirability bias in self-report,[40] and in reactivity during observation.[41] Self-reported breastfeeding practices could

lead to over-estimating the effect size as mothers exposed to the intervention might have exaggerated desirable behaviours. However, formative work revealed that the study population was already familiar with messaging on exclusive breastfeeding, so it is not clear that reporting would have differed between study groups. To date, a more robust indicator of breastfeeding behaviour than the WHO indicator with a 24-h recall period that could be used in intervention trials is not available. As outcome assessors were blinded to the intervention and were given only minimal information to enable them to assess exposure, it is possible that individuals who did not recall the intervention well would have been misclassified as unexposed. Effort was made to reduce subjectivity when outcomes were measured by self-report: the survey was preceded by structured observation and questions on infant feeding within the survey were preceded by general questions on the infant's birth and health. If the intervention caused caregivers in the intervention group to modify their behaviour, differential reactivity between study groups could result in over-estimation of the effect of the intervention.

The per-protocol analysis (table 4) needs to be interpreted with caution, as this effectively breaks the randomisation and generally carries a risk of confounding. By adjusting for baseline values of the outcomes we aimed at minimising this risk, but residual confounding cannot be fully excluded in such analysis. The outcome assessment was limited to a fixed area around each clinic (fried egg design). The results of this trial therefore only refer to the population living within the specified area around each clinic. Sensitivity analysis was done to assess whether selection bias was introduced as a result of oversampling in the intervention group. Comparison of equal numbers of intervention and control group participants by removing the extras sampled in each cluster widened confidence intervals but did not appreciably affect the effect estimates.

This trial was a proof of concept study of the Komboni Housewives intervention and hence it was not appropriate to measure health outcomes. As well as showing that a model based on emotional drivers might prompt change in exclusive breastfeeding behaviour, our results also exposed some issues that will need to be addressed before a multiple behaviour change campaign of this nature can be brought to scale in Zambia or anywhere else. The number of target behaviours and messages should be reviewed, the mechanism of change should be explored through process evaluation to learn whether the levers of change were appropriate for each behaviour and the cost-effectiveness of this approach should be assessed.

The Komboni Housewives intervention represents a new and different approach to behaviour change communication and was successful in improving exclusive breastfeeding behaviour and in increasing awareness of zinc. Improvements were also observed in ORS preparation and use of zinc in areas where the intervention reached more widely. Further investigation of factors that influenced these intervention effects and the paucity of effect on handwashing outcomes is warranted. The trial supports the case for continuing to develop novel interventions based on emotional drivers to improve behaviour related to childhood diarrhoea.

Contributors

KG designed the study with input from W-PS, JChip, and RC. The intervention was designed by a creative agency with technical input from VC, JChip, KG, and RC. Study implementation involved KG, JChip, ZS, MM, and JChil. KG analysed the data with input from W-PS and JL. KG drafted the manuscript and all co-authors contributed revisions to the manuscript. KG and JChip had full access to all the data in the study. KG made the final decision to submit for publication.

Declaration of interests

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